

REMARKS

Applicants concur that this application does not claim priority to U.S. Patent Application Serial No. 09/132,711, now U.S. Pat. No. 6,428,550, and withdraw that claim of priority from the preliminary amendment to the specification of September 18, 2000. That claim of priority appears to have been a typographical error by Applicants' former counsel.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 38, 43-46, 50-59

Claim 38 claims a system for deploying a unitary anastomosis device, comprising "a holder tube configured to hold the unitary anastomosis device with an attached graft vessel; and an expander positioned within the holder tube and slidable with respect to the holder tube to a position at which at least part of the expander is positioned within the unitary anastomosis device and radially expands the unitary anastomosis device."

U.S. Pat. No. 6,485,496 to Suyker ("Suyker") does not disclose each and every element of claim 38. For example, Suyker does not disclose a holder tube configured to hold the unitary anastomosis device with an attached graft vessel. In contrast, Suyker does not disclose a holder tube configured to hold a unitary anastomosis device. Rather, Suyker discloses a plurality of spaced-apart wedges 32 that hold an anastomosis device 1 (e.g., Figures 25, 27; column 6, lines 61-65) and a plurality of spaced-apart arms 51 that hold an anastomosis device 1 (e.g., Figures 31-34; column 8, lines 1-5). Neither spaced-apart wedges

32 nor spaced-apart arms 51 constitute a tube. Although Suyker discloses placing an anastomosis device 1 against the distal end 41 of a housing 40, Suyker does not disclose holding the anastomosis device with the distal end 41 of the housing 40, instead merely stating that the "distal end surface can serve as an anvil for annular element 1." (Figures 28, 30; column 7, lines 13-15). Thus, Suyker does not disclose the use of a holder tube or other tube to hold an anastomosis device 1.

Suyker discloses a sliding element 35, 44, 47 having at least one angled surface, and a plurality of engagement elements 32, 42, 51 that are contacted by the sliding element 35, 44, 47 as it translates and are thereby urged outward to deploy the anastomosis device 1. (e.g., Figures 25-27; 28-30; 31-34; column 6, lines 54-65; column 7, lines 21-26; column 8, lines 1-5 and 17-29). If the sliding element 35, 44, 47 is considered to be analogous to the claimed expander, which Applicants do not admit, then Suyker does not disclose a holder tube configured to hold an anastomosis device, but rather a plurality of spaced-apart arms or wedges that hold an anastomosis device, or a surface used as an anvil for the anastomosis device. Alternately, if the engagement elements 32, 42, 51 are considered to be analogous to the claimed expander, which Applicants do not admit, then Suyker does not disclose an expander that is slidable. Further, if the engagement elements 32, 42, 51 are considered to be analogous to the expander, then Suyker does not teach a separate holder tube, and necessarily cannot disclose an expander slidable relative to the holder tube. As a result, Suyker does not disclose each and every element of claim 38.

Thus, Suyker does not disclose each and every element claimed in claim 38, and Applicants consequently believe claim 38 is in condition for allowance. Claims 43-46 and 50-59 depend directly or indirectly from independent claim 38. Thus, dependent claims 43-46 and 50-59 are believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 47, 48

Claims 47 and 48 each depend from independent claim 38. As discussed above, Suyker does not teach or suggest all of the elements of claim 38. Because claims 47 and 48 depend from claim 38, claims 47 and 48 each include all the elements of claim 38. Thus, Bolduc neither teaches nor suggests all of the limitations of claims 47 and 48. Consequently, a *prima facie* case of obviousness has not been established, and Applicants believe that claims 48 and 49 are in condition for allowance under MPEP 608.01(n)(III).

Claims 60, 64-71

Amended claim 60 claims "a first member configured to hold the anastomosis device; a second member, said first member and said second member slidable relative to one another...and a handle connected to at least one of said first member and said second member, wherein rotation of said handle about an axis causes said first member and said second member to translate, and to translate relative to one another."

The Office Action states that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Suyker deployment device as taught by Gifford to add threads between the tubes 40 and 37, and between 37 and 44, to advance the device with more precision and force." However, claim 60 does not claim threads between the expander and the holder tube, nor are such threads disclosed in the specification. Thus, whether it may be obvious to add the threads of Gifford to the deployment device of Suyker is irrelevant to Claim 60.

Indeed, Gifford teaches away from using threads between two members that are slidable relative to one another, because engagement between the threads of the two members prevents the two members from sliding relative to one another. Thus, neither Gifford nor Suyker, alone or in combination, teach or suggest all of the limitations of claim 60. Applicants believe independent claim 60 is in condition for allowance. Because claims 64-71 depend from claim 60, Applicants believe that they are in condition for allowance as well under MPEP 608.01(n)(III).

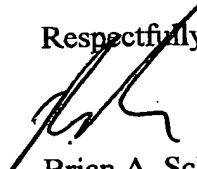
Claims 72, 76-84

The analysis performed above with regard to claims 60 and 64-71 applies equally here. Applicants believe that independent claim 72 is in condition for allowance. Because claims 76-84 depend from claim 72, Applicants believe that they are in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Entry of this amendment and allowance of pending claims 38-60, 64-72 and 76-84 are respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 326-5600 x162
Chief Patent Counsel
Cardica, Inc.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09.664.588	09-18 2000	Jaime Vargas	032405-003	4754

33109 7590 07 07 2003

CARDICA, INC.
171 JEFFERSON DRIVE
MENLO PARK, CA 94025

EXAMINER
DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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Paper No.

Notice of Non-Compliant Amendment (Voluntary Revised Practice)

The amendment, filed 6-26-03, under the voluntary revised amendment practice guidelines¹, published in the Official Gazette on February 25, 2003 (*Amendments in a Revised Format Now Permitted*, 1267 Off. Gazette 106), does not fully comply with minimal requirements of the voluntary practice. In order for the amendment to be entered, it must either (1) comply with the guidelines of the voluntary revised amendment practice (which practice invokes waivers of certain 37 CFR 1.121(a)-(d) requirements) or (2) comply with current 37 CFR 1.121 requirements.

THE FOLLOWING ITEM(S) IN APPLICANT'S AMENDMENT CAUSES THE AMENDMENT TO BE NON-COMPLIANT WITH THE VOLUNTARY REVISED AMENDMENT PRACTICE.

- ☒ 1. A complete listing of all of the claims is not present in the amendment paper.
- ☐ 2. The listing of claims does not include the text of all claims currently under examination.
- ☐ 3. The claims of this amendment paper have not been presented in ascending numerical order.
- ☐ 4. Each claim has not been provided with a status identifier, and, as such, the individual status of each claim cannot be determined.
- ☐ 5. Other: _____

LIE: Check one of the following boxes:

- ☐ **PRELIMINARY AMENDMENT:** Applicant is given ONE MONTH from the mail date of this letter to re-submit the amendment in compliance with either the guidelines of the revised amendment practice or current 37 CFR 1.121. Failure to comply with either the current 37 CFR 1.121 practice or with the voluntary practice will result in non-entry of the amendment and examination on the merits will commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
- ☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above-mentioned reply appears to be a *bona fide* response, applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit an amendment which complies with either the voluntary practice guidelines or current 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).

Tracie Hargreaves
Supervisory Legal Instruments Examiner (SLIE)

¹ For further explanation of the guidelines of the revised amendment format, please see the posted notice and sample amendment format at:
<http://www.uspto.gov/web/offices/pac/dapp/opla/prcognotice/officeflyer.pdf> and
<http://www.uspto.gov/web/offices/pac/dapp/opla/prcognotice/formatrevamdtpac.pdf>

March 18, 2003